

Attorney Docket No.: PTQ-0027
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REMARKS

Claims 56-59, 62-69, 71-84 and 87-102 are pending in the instant application. These claims have been subjected to restriction as follows:

Group I, claims 56, 62-69, 71-79, 97, 98, 101 and 102, drawn to a method of assessing cardiac damage by immunoreacting a biological sample with an antibody that binds specifically to one fragment of a myofilament protein, classified in class 436, subclass 518+;

Group II, claims 56-59, 62-69, 71-79, 97, 98, 101 and 102, drawn to a method of assessing cardiac damage by immunoreacting a biological sample with an antibody that binds specifically to two or more fragments of a myofilament protein, classified in class 436, subclass 518+;

Group III, claims 80, 81, 87-92 and 97-102, drawn to a method of assessing skeletal muscle damage by immunoreacting a biological sample with an antibody that binds specifically to one fragment of a myofilament protein, classified in class 436, subclass 518+; and

Group IV, claims 80-84, 87-92 and 97-102, drawn to a method of assessing skeletal muscle damage by immunoreacting a biological sample with an antibody that binds specifically

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to two or more fragments of a myofilament protein,
classified in class 436, subclass 518+.

Further, the Examiner suggests that claims of Groups I-IV are drawn to patentably distinct species. With respect to Groups I and III, the Examiner has requested election of one peptide identified by SEQ ID NO: or another unequivocal naming system. With respect to Groups II and IV, the Examiner has requested election of two peptides identified by SEQ ID NO: or another unequivocal naming system.

Applicants respectfully traverse this restriction requirement and species election requirement.

At the outset, it is respectfully pointed out that this patent application was filed in 1998 and therefore has been in prosecution for 6 years. Applicants already responded to two Restriction Requirements made by the prior Examiner in February of 2000 and November of 2001. Further, this is the second Request for Continued Examination filed in this case. Thus, there have been multiple exchanges between the previous Examiner and Applicants leading to the claims as they now stand. To receive yet a third Restriction Requirement in this case at this point in the prosecution history appears to be contradictive of MPEP 704.01 and 719.05. It also seems contradictive to the premise under which an RCE, a Request for Continued Examination, is filed.

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Had Applicants wanted to re-start the prosecution, a continuation application would have been filed, not a Request for Continued Examination.

In accordance with MPEP 704.01, it is respectfully requested that full faith and credit be given to the searches by Examiner Gucker. Neither an entirely new approach to the application nor an attempt to reorient the point of view of the previous Examiner should be taken. See MPEP 704.01. Withdrawal of this Restriction Requirement in light of the extensive prosecution history and reconsideration of rejoicing of the claims already searched and examined by Examiner Gucker is therefore respectfully requested.

Reconsideration of this Restriction Requirement is also respectfully requested as it does not meet the criteria for proper restriction as set forth in MPEP 803.

The first criteria for proper restriction is that the inventions be independent or distinct. The second criteria is that there would be serious burden on the Examiner if the restriction is not required. See MPEP 803.

The Examiner suggests that Groups I-IV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a

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non-coextensive search because of different starting materials, goals, personnel, patients and differing chances of success.

Applicants respectfully disagree.

At the outset, Applicants respectfully disagree that claimed methods require a non-coextensive search. Each of the Groups set forth by the Examiner are classified in the same class and subclass. Thus, any search of one of the Groups would clearly reveal art relating to the other Groups. Further, no additional searching of these claims is required as these claims have already been searched extensively by the previous Examiner.

In addition, contrary to the Examiner's suggestion, the goal of the claimed methods, namely to assess muscle damage, is the same. Further, the process steps are the same. Specifically, all claims require detecting the presence or absence or measuring the amount of a peptide fragment of a myofilament protein or a covalent or non-covalent complex of at least a peptide fragment of a myofilament protein and an intact myofilament protein or two peptide fragments of myofilament proteins, in a biological sample obtained from a subject being assessed for muscle damage, by incubating the biological sample with an antibody or a functional fragment of an antibody that specifically binds to the peptide

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fragment of a myofilament protein or covalent or non-covalent complex of at least a peptide fragment of a myofilament protein and an intact myofilament protein or two peptide fragments of myofilament proteins, under conditions which allow the antibody or functional fragment of the antibody to form a complex with the peptide fragment of a myofilament protein or covalent or non-covalent complex of at least peptide fragment of a myofilament protein and an intact myofilament protein or two peptide fragments of myofilament proteins. Further, all claims require detecting or measuring the formed complex.

Accordingly, since this Restriction Requirement does not meet the criteria for proper restriction as set forth in MPEP 803, withdrawal and rejoinder of all pending claims is respectfully requested.

In the event that all claims are not rejoined, reconsideration of rejoinder of at least Groups I and II, relating to cardiac muscle damage or Groups III and IV, relating to skeletal muscle damage is respectfully requested since all starting materials, process steps and goals of the method are identical and searching of the art relating to Group I or III would clearly reveal art relating to Group II or IV, respectively.

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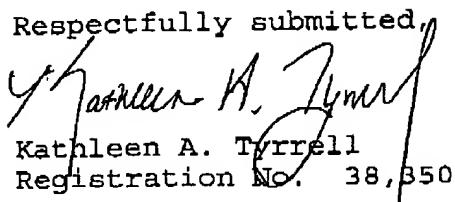
Reconsideration of the species election requirement is also respectfully requested.

MPEP § 808.01 states that an election of species should be made when a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required. In the instant case; however, the generic claims are not drawn to such a large multiplicity that search of all species would be unduly extensive or burdensome. Only five different peptides and fragments thereof, all of which fall under the generic class of myofilament proteins, are set forth in the claims. Accordingly, reconsideration of this species election requirement is respectfully requested.

In an earnest effort to be completely responsive to the Office Action of record, Applicants elect to prosecute Group III, more preferably Groups III and IV, with traverse. Further, with respect to the species election, Applicants elect troponin I, more preferably troponin I and myosin light chain 1, with traverse. In accordance with MPEP § 809.01 and 37 C.F.R. § 1.146, it is respectfully pointed out that the claims should only be restricted to this species if no generic claim is held allowable.

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Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

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